

1998. See 63 FR 29634 (June 1, 1998) and 1121 O.G. 82 (June 23, 1998)

2421 Overview of the Sequence Rules

2421.01 Applications Affected

The sequence rules require the use of standard symbols and a standard format for sequence data in most sequence-type patent applications. They further require the submission of that data in computer readable form. Compliance is required for most disclosures of sequence data in new applications filed on or after October 1, 1990. The revised sequence rules apply to most new applications filed on or after July 1, 1998. See the final rule publications as cited in MPEP § 2420 for more detailed applicability information.

The Office encourages voluntary compliance for applications not subject to the rules, but all aspects of the rules must be complied with before data will be entered into the database. This includes submission of all statements required by the rules. In exceptional circumstances, it should be noted that the Office may waive the rules via a 37 CFR 1.183 petition.

2421.02 Summary of the Requirements of the Sequence Rules

Basically, the sequence rules define a set of symbols and procedures that are both mandatory and the only way that an applicant is permitted to describe information about a sequence that falls within the definitions used in the rules. Thus, 37 CFR 1.821 defines a sequence for the purpose of the rules, the requirements for specific symbols, formats, paper and computer readable copies of the sequence, and the deadlines for complying with the requirements. 37 CFR 1.822 to 37 CFR 1.824 set forth detailed descriptions of the requirements that are mandatory for the presentation of sequence data, and 37 CFR 1.825 sets forth procedures that are available to an applicant in the event that amendments to the sequence information or replacement of the computer readable copy become necessary.

The sequence rules embrace all unbranched nucleotide sequences with ten or more bases and all unbranched, non-D amino acid sequences with four or more amino acids. The rules apply to all sequences in a given application, whether claimed or not. All such sequences are relevant for the purposes of building a com-

prehensive database and properly assessing prior art. It is therefore essential that all sequences, whether only disclosed or also claimed, be included in the database.

2421.03 Notification of a Failure to Comply

With respect to the Office's determination of compliance with the sequence rules and the opportunities afforded applicants to satisfy the requirements of the rules, applicants will be notified of easily detectable deficiencies early in the application process. Deficiencies of a more sophisticated nature will likely only be detected by the examiner to whom the application is assigned. Applicants whose computer readable forms are damaged in the mail, are not readable, or are missing mandatory elements will be notified shortly after receipt of the application by the Office. Other errors or inconsistencies will be noted by the examiner early in the examination process. Upon detection of damage or a deficiency, a notice will be sent to the applicant detailing the damage or deficiency and setting at least a 30-day period for reply. The period for reply will usually be 1 month. However, if the notice is sent out with an Office communication having a longer period for reply, the period for reply may be longer than 1 month, e.g., where the notice is sent with an Office action on the merits setting a 3-month period for reply. Extensions of time in which to reply will be available pursuant to 37 CFR 1.136. When an action by the applicant, such as a reply to a Notice to Comply from the Office, is determined to be a *bona fide* attempt to comply with the rules and it is apparent that compliance with some requirement has inadvertently been omitted, the applicant may be given a new time period to correct the omission. See 37 CFR 1.135(c). The relevant form paragraphs and a copy of the Notice to Comply to be used in applications subject to the sequence rules are included in MPEP § 2427 through § 2427.02.

A notification of a failure to comply with the sequence rules will usually be accompanied by an analysis of a submitted computer readable form. Any inquiries regarding a specific computer readable form that has been processed by the Office should be directed to the Systems Branch of the Chemical/Biotechnology Division of the Scientific and Technical Information Center.

2421.04 Future Changes to the Sequence Rules

With general regard to the symbols and format to be used for nucleotide and/or amino acid sequence data set forth in 37 CFR 1.822 and the form and format for se-

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